Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2262181	07/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
David De Vinck, Pa	5 Prospect Place, Pompton Plains, NJ	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with the Laboratory Director (LD), the laboratory failed to have a procedure for a Biannual Assesment for Histopathology testing from 6/10/22 to the date of survey. The LD confirmed on 7/24/24 at 1:30 pm that the laboratory failed to have the above mentioned procedure.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals

	(normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with the Laboratory Director (LD), the laboratory failed to have all applicable procedures for Histopathology tests in the PM from 6/10/22. The finding includes: 1. The laboratory failed to have the laboratories requirements for specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection for Histopathology testing. 2. The LD confirmed on 7/24 /24 at 1:45 pm that the PM did not have the above mentioned procedures.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) records and interview with the Laboratory Director (LD) the laboratory failed to document Hematoxylin and Eosin (H&E) control slide reactions for Histopathology testing from 6/10/2022 to the date of survey. Approximately 6000 patients where read and reported. The LD confirmed on 7 /24/24 at 1:30 pm that the laboratory did not document H&E QC stain reactions.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on the lack of Biannual Assessment (BA) records and interview with the Laboratory Director (LD), the LD failed to ensure BA was performed to evaluate the laboratory's performance accurately 6/10/22 to the date of survey. The LD confirmed on 7/24/24 at 1:00 pm the BA was not performed to evaluate the laboratory's performance accurately.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established

	and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD) The LD failed to establish a Quality Control (QC) program for Histopathology from 6/10/21 to the date of survey. The LD confirmed on 7/24/24 at 1:00 pm that a QC program was not established and maintained.